UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/361,542	07/27/1999	DOUGLAS JOSEPH DOBROZSI	7247M	5652

27752 7590 04/23/2003

THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
WINTON HILL TECHNICAL CENTER - BOX 161
6110 CENTER HILL AVENUE
CINCINNATI, OH 45224

EXAMINER	
PULLIAM, AMY E	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/361,542	DOBROZSI, DOUGLAS JOSEPH	
	Examiner	Art Unit	
	Amy E Pulliam	1615	

-- The MAILING DATE of this communication appears on the cov r sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-39 and 41-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-39 and 41-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Request for Extension of Time, Request for Continued Examination, and Preliminary Amendment F, all received by the Office February 10, 2003.

Status of Claims

Applicant has amended the current method claims to require that the composition is aqueous. Additionally, Applicant has canceled claim 40, added claims 42-48, and currently claims 36-39, and 41-48 are pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 43-45 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 733 357 to Boltri *et al.*.

Boltri *et al.* disclose a formulation which is nebulizable by a mechanical pump, containing colloidal silica abstract). Boltri *et al.* teaches that the composition comprises colloidal silica in an amount from 2% to 15%, and a pharmaceutically active agent, as well as water and other additional excipients conventionally used in pharmaceutical techniques (p 2, l

22-26). Boltri *et al.*. additionally teach that the average diameter of the silica particles is between 7 and 40 nanometers, which reads on Applicant's claim to less than 1 micron.

The examiner recognizes that this reference was used previously in the rejection of paper number 13, and that this rejection was later withdrawn. However, the examiner points out that the claims rejected in paper number 13 were drawn to an oral, mucoretentive, aqueous liquid composition, as well as a few method claims. In Applicant's response to paper number 13, all of the rejected claims were canceled, and new claims 30-35, drawn to a method of providing a mucoadhesive coating the mucosa of the esophagus, stomach, and small intestine, were added. Applicant's arguments with regards to the Boltri reference were focused around the pending claims at that time, which were drawn only to the method of providing a mucoadhesive coating. The examiner points out that there are no claims currently drawn to this method. Instead, the current claims are drawn to a composition, and a method of administering an active agent.

The generic composition claim requires an aqueous, liquid composition, comprising from about 2% to about 50% of colloidal particles of silica, and an active agent. Boltri *et al.* clearly teach the limitations of broad claim 43. The reference additionally anticipates the limitations of claims 44 and 45, teaching both the percent of colloidal silica, and the particle size.

The generic method claim requires a method of administering an active to one or more of the esophagus, stomach, or small intestine by swallowing the composition described above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 43-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boltri *et al.*, as discussed above.

Boltri *et al.* do not specifically teach that the composition be an oral composition. However, this is not considered for two reasons. One, this is a future intended use of the composition. It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinquish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Additionally, this limitation is found in the preamble of the claim. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Additionally, Boltri *et al.* do not teach that citric acid, or a salt thereof, is included in the composition. However, Boltri *et al.* do teach that any excipients conventionally used in

pharmaceutical formulations can be present (p 2, l 24-26). It is the position of the examiner that citric acid is a well known pharmaceutical excipient, and it would be obvious and unpatentable to include a well known pharmaceutical excipient in a pharmaceutical composition. For reiteration, the examiner relies on the International Cosmetic Ingredient Dictionary and Handbook to show that both citric acid and sodium citrate are known excipients, for example, as pH adjusters.

One of ordinary skill in the art would have been motivated to create an aqueous, liquid, composition containing colloidal silica, an active agent, and appropriate excipients, based on the teachings of Boltri *et al.*. The expected result of the composition would be a successful pharmaceutical formulation. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 36-39, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 4,915,948 to Gallopo *et al.*. Gallopo *et al.* teach a tablet having improved bioadhesion to mucous membranes (abstract). Gallopo *et al.* teach that the teach the inclusion of colloidal silica particles, for example fumed silica (c 7, l 47), as well as active agents (c 8, l 9+). Additionally, Gallopo *et al.* teach the inclusion of additives such as citric acid (c 7, l 39). Gallopo *et al.* do not teach the claimed percentage and particle size of the silica particles. However, it is the position of the examiner, that absent a showing of criticality, the determination of particular percentages and particle sizes is within the skill of the ordinary worker as part of the process or normal optimization. Specifically because Gallopo *et al.* teach a successful pharmaceutical formulation. Additionally, Applicant's claimed percentages span a large range, from a very small amount (2%) to half the composition (50%). This reiterates that the particular

amount is manipulatable. Additionally, Gallopo *et al.* does not specifically teach "a method of administering an active agent to one of more of the esophagus, stomach, and small intestine by swallowing...." However, Gallopo *et al.* do teach an oral pharmaceutical composition, that comprises colloidal silica particles, active agent, and citric acid. Furthermore, Gallopo *et al.* teach that the composition has improved bioadhesion to the mucus membrane. One of ordinary skill in the art would understand that an orally administratable table, which has an increased bioadhesion to mucous membranes, suggests Applicant's claimed method of administering an active agent to the esophagus, stomach, and/ or small intestine. Particularly because this is the path an active agent will follow after oral administration. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

THURMAN K PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600